OCT 1 9 2000

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K002257

1. Submitter's Identification:

Tecno Instruments (PVT) Ltd.
316-C Small Industrial Estate
Sialkot – 51340
Pakistan

Contact: Mr. Haseeb A. Bhatti
Marketing Director

Date Summary Prepared: July, 2000

2. Name of the Device:

Tecno Disposable Fingerswitch Pencil, Model 150-100

3. Predicate Device Information:

Valleylab, Inc., K# 813071, Disposable Handswitching Pencil, Model E2516H, and K# 955109, VL2600 Handswitching Pencil with Holster, Valleylab, Inc., Boulder, Co.

4. Device Description:

With its intended use to remove tissue and control bleeding by use of high frequency electrical current, the subject device is an electrosurgical hand-activated electrode (pencil) with an attached cable (connecting cord). It consists of a plastic body with two (2) activation (pushbutton) switches (yellow and blue-cutting and coagulation) on the topside, a removable electrode, and a hardwired cable with a molded 3-prong plug that connects to the electrosurgical unit (ESU). Enclosed in the plastic body is a PCB that supplies high frequency current to the electrode on one end and is attached with PVC 3-core cable on the other end. The connecting cable is attached with molded socket with three (3) standard banana plugs (4.0 mm). At the front end, a detachable blade electrode is attached.

5. Intended Use:

The Tecno Disposable Fingerswithch Pencil, Model 150-100, is intended for use in general surgical procedures to deliver electrosurgical energy to the surgical site for tissue cutting and coagulation. The device is single use only and is supplied sterile with a blade electrode. The device may be used with electrosurgical generators which accept a standard three-pin plug.

6. Comparison to Predicate Devices:

The Tecno Disposable Fingerswitch Pencil, Model 150-100 is substantially equivalent to the Valleylab Disposable Handswitching Pencil, Model E2516H, K# 813071 and the Valleylab Handswitching Pencil with Holster, Model VL2600, K# 955109, as well as other legally-marketed electrosurgical pencils: it has pushbutton switches, a removable electrode and a hardwired cable with a molded three-prong plug that connects to the ESU.

The Tecno Disposable Fingerswitch Pencil is similar to the Valleylab predicates in its intended use, safety and efficacy, design specifications, power source and performance criteria. The Tecno device may differ from the predicates in color and size. However, these differences raise no issues of safety or effectiveness.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Tecno Disposable Fingerswitch Pencil, Model 150-100 in the intended environment of use is supported by testing that was conducted in accordance with the FDA May 10, 1995 "510(k) Guidance Document for General Surgical Electrosurgical Devices", which outlines performance requirements. In addition, all applicable requirements of the ANSI/AAMI HF-18-1993, American National Standard for Electrosurgical Devices were performed.

Testing was conducted on the Tecno Disposable Fingerswitch Pencil, Model 150-100 device per ANSI/AAMI HF-18 requirements. None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or HF-18 Standard or resulted in any safety hazards. We concluded that testing met all relevant requirements of the aforementioned standard.

In addition, ISO 10993 Biocompatibility Testing requirements were met, as well as ANSI/AAMI/ISO 11137-1995 Radiation Sterilization Standard requirements.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

We have demonstrated that the Tecno Disposable Fingerswitch Pencil, Model 150-100 is as safe and effective as the predicate device, based on the ANSI/AAMI HF-18-1993 American National Standard for Electrosurgical Devices, as well as the FDA 510(k) Guidance Document for General Surgical Electrosurgical Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

Tecno Instruments (PVT) Ltd.
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K002257
Trade Name: Tecno Disposable Fingerswitch Pencil, Model 150-100
Regulatory Class: II
Product Code: GEI
Dated: July 21, 2000
Received: July 25, 2000

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K002257

Device Name Tecno Disposable Fingerswitch Pencil, Model 150-100

Indications For Use:

The Tecno Disposable Fingerswithch Pencil, Model 150-100, is intended for use in general surgical procedures to deliver electrosurgical energy to the surgical site for tissue cutting and coagulation. The device is single use only and is supplied sterile with a blade electrode. The device may be used with electrosurgical generators which accept a standard three-pin plug.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002257

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**